PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

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Christine Todd Whitman, Administrator
Environmental Protection Agency
Ariel Rios Building (1101A)
1200 Pennsylvania Ave. NW
Washington, DC 20460

Re: Comments on ACC's Polybutylene Succinic Anhydride Category

Dear Administrator Whitman,

The following are comments on the American Chemistry Council's revised test plan for the Polybutylene Succinic Anhydride Category. These comments are submitted on behalf of People for the Ethical Treatment of Animals (PETA), the Physicians Committee for Responsible Medicine (PCRM), the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal and environmental protection organizations have a combined membership of more than ten million Americans.

Overall, we appreciate the fact that the ACC is using existing data from the compounds in this category and other categories to assess their toxicity. However, the compounds in this category should be included in a single larger category—at least including the alkenyl succinic anhydride compounds. Comments on the alkenyl succinic anhydride category have been submitted in a separate document and should be used in order to eliminate the need for any new animal testing.

Testing Issues

The ACC has expressed an admirable desire to minimize the use of animals in the HPV program. The only new test proposed here is the *in vitro* chromosomal aberration assay. ACC does not state the cell type to be used in the *in vitro* chromosomal aberration assay. Although this is considered to be an *in vitro* assay, it is not non-animal, as various animal tissues are used (Chinese hamster ovary or lung cells, human or rat lymphocytes, or human, rat or mouse bone marrow). We recommend that human lymphocytes be used to eliminate the need to use animals to test this endpoint.

All mammalian SIDS tests are deferred in this test plan pending the outcome of a repeat dose study and a 1-generation study with the structurally related chemicals addressed in the ACC test plan for the alkenyl succinic anhydride category. As noted in our comments on the ACC test plan for the alkenyl succinic anhydride category, neither of the above tests are appropriate for that category, and for the same reasons, they would not be appropriate for the polybutylene succinic anhydride category. The overall category should be expanded to include both groups and, for reasons stated below and in the comments on the alkenyl succinic anhydride category, no additional mammalian or fish testing is appropriate for either category.

Category Issues

We commend the ACC for combining the two anhydride compounds into a single category. This categorization is logical and straightforward. However, the compounds in this category should be further evaluated in light of the information gained from other similar compounds such as those found in Dupont's Dicarboxylic Acid Category, where high molecular weight dicarboxylic acids were found to have low toxicities. The compounds in this category are likely to have even lower toxicities, as the molecular weights are heavier and all the chemical/physical properties of these chemicals point to very low mobilities. The vast weight of evidence for these compounds with long branched alkane/alkenes chains with a polar end to them shows that they tend to have very low toxicities. Furthermore, the exposure to workers and consumers of chemicals in this category will typically be as trace or minor constituents in lubricating oils or their additives, so that exposure will be at dramatically lower levels than the levels of testing that have already been conducted.

Thank you for your attention to these comments. The organizations listed in the introductory paragraph of these comments request that the ACC contact us directly to discuss these concerns.

Sincerely,

Jessica Sandler
Federal Agency Liaison